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ORIGINAL ARTICLE / ÖZGÜN MAKALE

Early-term results of percutaneous pulmonary valve implantation (valve-in-valve) in dysfunctional bioprosthetic valves in pulmonary position

Pulmoner pozisyondaki disfonksiyonel biyoprotez kapak içine perkütan pulmoner kapak implantasyonunun (kapak-içine-kapak) erken dönem sonuçları

Ensar Duras, Erman Çilsal, Selman Gökalp, Sezen Ugan Atik, Murat Şahin, Bekir Yükcü, Alper Güzeltaş

Department of Pediatric Cardiology, University of Health Sciences, İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, İstanbul, Türkiye

ABSTRACT

Background: This study aimed to assess the outcomes of valve-in-valve implantation within previously placed bioprosthetic valves.

Methods: This single-center retrospective study included patients who underwent percutaneous valve-in-valve procedures between July 2014 and September 2023. These patients had previously received pulmonary bioprosthetic valves via surgical or transcatheter methods.

Results: The study included 20 patients (13 males, 7 females; mean age: 20.4±7.1 years; range, 10.8 to 35.8 years). Preprocedural assessment revealed stenotic dysfunction in 12 patients, regurgitant dysfunction in two patients, and a combination of both in six patients. Following implantation, there was a notable improvement in invasive measurements; systolic right ventricular pressure decreased from 64.0±24.5 mmHg to 31.3±6.7 mmHg (p<0.001), right ventricular outflow tract gradient from 44.0±23.2 mmHg to 7.6±5.8 mmHg (p<0.001), and echocardiographic pulmonary regurgitation grade from 2.1±1.2 to 0.2±0.4 (p<0.001). The median time between initial bioprosthetic pulmonary valve placement and valve-in-valve procedure was 8.2 years (IQR, 6.2 to 9.9 years). The median follow-up duration was 24.8 months (IQR, 8.3 to 40.2 months). Only one patient required a repeat PPVI procedure 10 years after the valve-in-valve procedure, while no other patients required reintervention during the follow-up period.

Conclusion: Valve-in-valve implantation within previously placed bioprosthetic valves is a feasible and safe approach, offering symptom relief and eliminating the need for further surgical interventions.

Keywords: Bioprosthetic valve, interventional cardiology, percutaneous pulmonary valve implantation, tetralogy of Fallot, valve-in-valve.

ÖZ

Amaç: Bu çalışmada, daha önce yerleştirilmiş biyoprotez kapaklar içine kapak implantasyonunun sonuçları değerlendirildi.

Çalışma planı: Bu retrospektif çalışma, tek bir merkezde Temmuz 2014 - Eylül 2023 arasında perkütan kapak-içine-kapak işlemi uygulanan hastaları içerdi. Bu hastalara daha önce cerrahi veya transkateter yöntemlerle pulmoner biyoprotez kapaklar yerleştirilmişti.

Bulgular: Çalışmaya 20 hasta (13 erkek, 7 kadın; ort. yaş: 20.4±7.1 yıl; dağılım, 10.8-35.8 yıl) dahil edildi. İşlem öncesi değerlendirmede, 12 hastada darlığın ön planda olduğu disfonksiyon, iki hastada yetersizliğin ön planda olduğu disfonksiyon ve altı hastada her iki tür disfonksiyon kombine olarak tespit edildi. İmplantasyon sonrasında invaziv ölçümlerde belirgin bir iyileşme görüldü; sistolik sağ ventrikül basıncı 64.0±24.5 mmHg'dan 31.3±6.7 mmHg'ya (p<0.001), sağ ventrikül çıkış yolu gradiyenti 44.0±23.2 mmHg'dan 7.6±5.8 mmHg'ya (p<0.001) ve ekokardiyografik pulmoner yetersizlik derecesi 2.1±1.2'den 0.2±0.4'e (p<0.001) düştü. İlk biyoprotez pulmoner kapak yerleştirilmesi ile kapak-içine-kapak işlemi arasındaki ortanca süre 8.2 yıl (IQR, 6.2-9.9 yıl) idi. Ortanca takip süresi 24.8 ay (IQR, 8.3-40.2 ay) idi. Sadece bir hasta kapak-içine-kapak işleminden 10 yıl sonra tekrarlanan perkütan pulmoner kapak implantasyonu işlemine ihtiyaç duydu ve takip süresi boyunca diğer hiçbir hastada yeniden müdahale gereksinimi olmadı.

Sonuç: Önceden yerleştirilmiş biyoprotez kapaklar içine yapılan kapak-içine-kapak implantasyonu, semptomları hafifleten ve ek cerrahi müdahale ihtiyacını ortadan kaldıran uygulanabilir ve güvenli bir yaklaşımdır.

Anahtar sözcükler: Biyoprotez kapak, girişimsel kardiyoloji, perkütan pulmoner kapak implantasyonu, Fallot tetralojisi, kapak-içine-kapak.

Corresponding author: Alper Güzeltaş.
E-mail: alperguzeltas@hotmail.com

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After surgical treatment of congenital heart diseases, issues in the right ventricular outflow tract (RVOT) are a common cause of reinterventions.[1] Postoperative pathologies such as RVOT stenosis, pulmonary regurgitation (PR), or both require surgical or catheter-based reintervention. Surgical options for RVOT reconstruction include valved conduits, homografts, mechanical, or bioprosthetic valves (BPVs), while interventional procedures involve the use of BPVs.[2-4] However, in patients with tetralogy of Fallot, the reported freedom from repeat pulmonary valve intervention after pulmonary valve replacement (PVR) is 74% within seven years.[5] Bioprosthetic valves inevitably develop dysfunction.[6,7] To eliminate the need for repetitive sternotomy-requiring operations, less invasive catheter-based interventions have been developed to treat pulmonary valve dysfunction.[8,9] This study aimed to report our percutaneous valve-in-valve (ViV) results in patients who had underwent surgical or transcatheter BPV implantation.

PATIENTS AND METHODS

All patients who underwent transcatheter ViV procedures on BPVs implanted surgically or through transcatheter means in the pulmonary position at the İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, Department of Pediatric Cardiology between July 2014 and September 2023 were retrospectively evaluated. Patients who underwent transannular patch repair, conduit correction, or valve-sparing surgical correction of the RVOT were excluded from the study. The study protocol was approved by the İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital Clinical Research Ethics Committee (date: 26.12.2023, no: 2023.10-92). Written informed consent was obtained from all participants. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All cardiac catheterization reports, surgical operation notes, and transthoracic echocardiography (TTE) reports of the patients were reviewed. Transthoracic echocardiography was performed using a Philips Epiq 7 (Philips Medical Systems, Bothell, WA, USA). The data included patient demographics, primary diagnosis, surgical procedure, type and size of biological material used, and precatheterization TTE data. Catheterization data included indications, pre- and postintervention hemodynamics (RVOT gradient, systolic right ventricle pressure [RVP], pulmonary artery pressure, and RVP/aortic pressure ratio [RVP/Ao]), interventions performed, adverse events, and the incidence and timing of subsequent transcatheter or surgical reinterventions. Indications for the procedure were increased RVP resulting from outflow tract obstruction (RVP/systemic pressure ratio >0.66), significant PR, right ventricle (RV) dilatation, or RV failure.[10]

Echocardiographic assessment

All patients underwent TTE before and within 24 h after the percutaneous ViV procedure, and instantaneous peak pressure changes, RVPs, and PR grades were reported. Echocardiographic evaluation was performed at three months, six months, and one year after the procedure. The systolic RVP was estimated from the tricuspid regurgitation jet, and the degree of PR was determined based on the appearance of the regurgitant jet using color flow Doppler. The severity of PR was graded as follows: 0, none or trivial; 1, mild (no retrograde diastolic flow in the pulmonary trunk with a detectable regurgitant jet at the right ventricular outflow); 2, moderate (retrograde diastolic flow in the main pulmonary artery); 3, severe (additional retrograde diastolic flow in the pulmonary artery branch); 4, free regurgitation (retrograde diastolic flow of the entire flow from the pulmonary artery branches).

Procedural details

All procedures were performed under general anesthesia. The femoral vein was used for vascular access. In addition, simultaneous femoral artery catheterization was performed for invasive arterial pressure monitoring and, in rare cases, for coronary artery assessment. Standard right heart catheterization and hemodynamic assessment were performed before and after valve implantation. Diagnostic angiography (RVOT, main PA, and branches) was performed to assess PR and determine the appropriate valve placement position. Valve dysfunction was classified as predominantly stenotic (peak-to-peak pressure gradient >40 mmHg in the RVOT), predominantly regurgitant (moderate or greater PR), or combined (peak-to-peak pressure gradient >40 mmHg in the RVOT and moderate or greater PR).

The diameter of the selected prosthetic valve (18 to 29 mm) was chosen to be equal to or up to 3 mm larger than the internal diameter of the BPV. The ViV aortic digital application (UBQO, London, England, UK) developed by and Dr. Vinayak Bapat was used for this purpose. Estimates were made based on the previously used valve size. Multiple balloon angioplasties using

high-pressure balloons of increasing size were performed prior to the ViV procedure to achieve the maximum diameter of the RVOT. The valve compatible with the maximum diameter achieved after balloon angioplasty was preferred. In those who had previously undergone percutaneous pulmonary valve implantation (PPVI), the same size as the original PPVI was chosen. However, in three patients, we used a larger valve compared to the previous PPVI. Prestenting (39-mm Andra stent; AndraMed, AndraMed, Reutlingen, Germany; 43-mm Optimus XL stent; AndraTec, AndraTec, Koblenz, Germany; 39-mm and 45-mm Covered CP stent; NuMED Inc., NuMED Inc., Hopkinton, NY, USA) was performed in four patients (two with initial prosthetic valve implantation by transcatheter approach and two by surgical implantation) prior to the percutaneous ViV procedure. In all four patients, balloon angioplasty failed to achieve complete relief of the RVOT stenosis, and prestenting was performed. Valve implantation was carried out using established routine methods. Briefly, a long sheath (Mullins Guiding Sheath, sizes 14F to 18F; Cook, Bloomington, IN, USA) was positioned into one of the pulmonary artery branches through an extra stiff exchange guidewire (Amplatz Extra Stiff; Cook, Bloomington, IN, USA) if stenting was planned, and a transcatheter pulmonary valve (Medtronic Melody, [Medtronic Inc., Minneapolis, Minn, USA]; Edwards Sapien, [Edwards Lifesciences Inc., Irvine, Ca, USA]; Meril's Myval, [Meril Life Sciences, India]) was positioned in the appropriate location with the intended delivery system. There was sufficient landing zone for placement of the new prosthetic valve in both the group with previous PPVI and the group with surgical PVR. From a technical perspective, there was no difference in procedure complexity between the two groups.

Angiography and hemodynamic measurements were repeated after implantation. Cefazolin (50 mg/kg per dose) was administered intravenously prior to catheterization and every 8 h for a total of 3 doses. Heparin sulphate (100 IU/kg) was administered in the catheterization laboratory. Upon discharge, low-dose aspirin (3 to 5 mg/kg/day) was prescribed for a period of six months.

Statistical analysis

All statistical analyses were performed using Jamovi software version 2.3. Descriptive statistics were used for patient and procedural data and were presented as median (interquartile range [IQR]). Categorical variables were expressed as numbers and percentages. The Wilcoxon test was used for repeated consecutive measurements, and follow-up data were analyzed using Friedman's one-way repeated measures analysis of variance. The Kaplan-Meier method was used to determine long-term outcomes and freedom from reintervention. Statistical significance was defined as a p-value <0.05.

RESULTS

In our center, between July 2014 and September 2023, PPVI was successfully completed in 236 (95.9%) out of the planned 246 patients (Figure 1). In five (2%) patients, RVOT anatomy was unsuitable for valve placement, and the procedure was

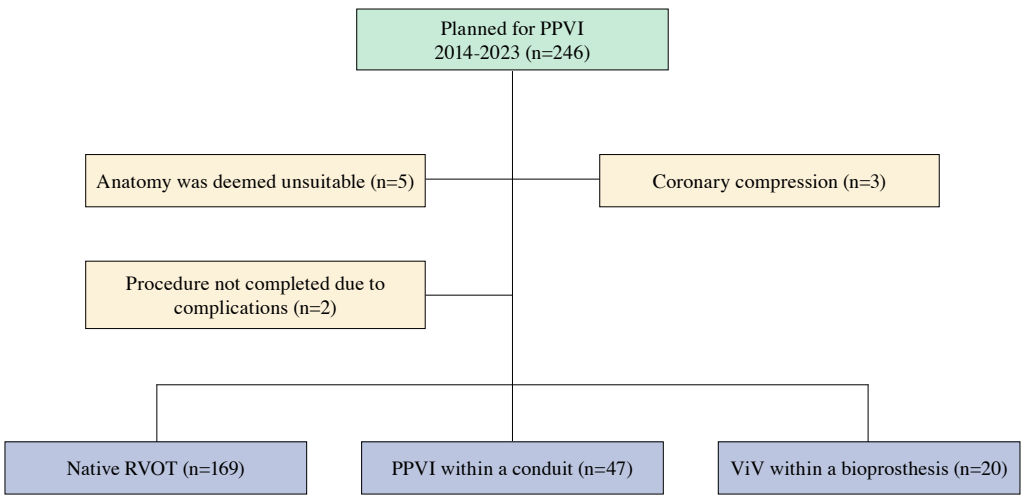

Figure 1. Flowchart of patients planned for PPVI.
PPVI: Percutaneous pulmonary valve implantation; RVOT: Right ventricular outflow tract; ViV: Valve-in-valve.

discontinued due to coronary compression observed during balloon tagging in three (1.2%) patients. In two (0.8%) patients, the procedure was discontinued due to procedural complications (balloon rupture and stent embolization). None of these 10 patients underwent procedures planned with a ViV approach. Of the remaining 236 patients, 20 (8.1%; 13 males, 7 females; mean age: 20.4±7.1 years; range, 10.8 to 35.8 years) underwent ViV within a BPV. All ViV patients were evaluated on the basis of preprocedural imaging modalities, as shown in the algorithm in Figure 1. The ViV procedure was successfully completed in all patients selected in accordance with these criteria. These 20 patients had previously undergone PVR in the pulmonary position, either percutaneously (n=6) or surgically (n=14). The median weight of the patients was 54.5 kg (IQR, 48.5 to 73.5 kg), and the median body surface area was 1.51 m^2 (IQR, 1.4 to 1.8 m^2). Tetralogy of Fallot or its variants was the most commonly observed cardiac pathologies. The median time from BPV implantation to percutaneous ViV procedure was 24.8 months (IQR, 8.3 to 40.2 months). The primary indication for ViV was BPV stenosis in 12 (60%) patients, regurgitation in two (10%) patients, and combined pathology in six (30%) patients. The most common clinical symptom was dyspnea (Table 1).

Previously surgically placed BPVs included Biocor, St Jude Medical, Inc., St Paul, Minn, USA (n=7, 23 to 25 mm), Sorin Soprano and Sorin Mitroflow, Sorin Biomedica SpA., Saluggia, Italy (n=4, 19 to 27 mm), Carpentier-Edwards, Edwards Lifesciences Inc., Irvine, Ca, USA (n=2, 23 to 27 mm), and Freestyle valve, Medtronic Inc., Minneapolis, Minn, USA (n=1, 19 mm). In addition, percutaneously implanted valves included Edwards Sapien, Edwards Lifesciences Inc., Irvine, Ca, USA (n=5, 23 to 29 mm) and Medtronic Melody, Medtronic Inc., Minneapolis, Minn, USA (n=1, 18 mm). The valves used in the percutaneous ViV procedure and the distribution of patients diagnoses are summarized in Table 2.

Procedural data

Percutaneous ViV was performed in all patients via the femoral vein under general anesthesia. Invasive right ventricular pressures decreased from 64.0±24.6 mmHg to 31.3±6.7 mmHg ($p<0.001$), RVOT pressure gradients decreased from 44.0±23.2 mmHg to 7.6±5.8 mmHg ($p<0.001$), and RVP/Ao decreased from 0.67±0.2 to 0.33±0.07 ($p<0.001$; Table 3). Angiography after PPVI showed a significant improvement in PR (Figure 2). In one patient, balloon angioplasty was performed simultaneously on the left pulmonary artery during the procedure.

Table 1. Demographic data and diagnostic details (n=20)

Variables	n	%	Median	IQR
Age (year)			18.7	15.2-24.7
Sex				
Male	13	65		
Weight (kg)			54.5	48.5-73.5
Body surface area (m^2)			1.51	1.4-1.8
Symptom				
Exercise intolerance	10	50		
Palpitation	5	25		
Asymptomatic	5	25		
Indications				
Predominant stenosis	12	60		
Predominant regurgitation	2	10		
Combined lesion	6	30		
Procedure duration (min)			62.5	36.3-75.0
Fluoroscopy time (min)			12.8	9.0-21.5
Length of hospital stay (day)			2	1.25-2
Follow-up duration after ViV (month)			24.8	8.3-40.2

IQR: Interquartile range; ViV: Valve-in-valve.

Table 2. Diagnosis distribution of patients and characteristics of the material used

Patient no	Diagnosis	Previous BPV implantation type	BPV type	BPV size (mm)	Duration from BPV implant to ViV (years)	Indication	ViV type	ViV size (mm)
1	TOF	Percutaneous	Medtronic Melody	18	6.4	Stenosis	Medtronic Melody	18
2	DORV-PS	Percutaneous	Edwards Sapien	23	7.0	Stenosis	Edwards Sapien	23
3	TOF	Percutaneous	Edwards Sapien	23	3.5	Regurgitation	Edwards Sapien	23
4	TOF	Percutaneous	Edwards Sapien	20	8.7	Stenosis	Meril's Myval	21.5
5	TOF	Percutaneous	Edwards Sapien	29	5.3	Combined	Meril's Myval	29
6	TOF	Percutaneous	Edwards Sapien	23	3.9	Stenosis	Meril's Myval	26
7	TOF	Surgery	Edwards Lifesciences	27	9.8	Stenosis	Meril's Myval	26
8	Congenital PS	Surgery	Edwards Lifesciences	23	10.4	Combined	Edwards Sapien	23
9	TOF	Surgery	Medtronic Freestyle	19	12.4	Stenosis	Edwards Sapien	23
10	TOF	Surgery	Sorin - Mitroflow	19	7.7	Stenosis	Medtronic Melody	18
11	TOF	Surgery	Sorin - Soprano	22	15.3	Regurgitation	Meril's Myval	26
12	ASD-PS	Surgery	Sorin- Mitroflow	27	6.6	Stenosis	Meril's Myval	26
13	TOF	Surgery	Sorin- Mitroflow	21	2.7	Stenosis	Meril's Myval	21.5
14	Congenital PS	Surgery	St. Jude - Biocor	25	15.6	Stenosis	Edwards Sapien	23
15	TOF	Surgery	St. Jude - Biocor	23	8.8	Stenosis	Edwards Sapien	23
16	TOF	Surgery	St. Jude - Biocor	25	9.6	Combined	Edwards Sapien	23
17	TOF	Surgery	St. Jude - Biocor	25	5.5	Combined	Meril's Myval	23
18	TOF	Surgery	St. Jude - Biocor	25	8.7	Combined	Meril's Myval	26
19	TOF	Surgery	St. Jude - Biocor	25	7.7	Stenosis	Meril's Myval	24.5
20	TOF	Surgery	St. Jude - Biocor	25	10.9	Combined	Meril's Myval	23

BPV: Bioprosthetic valve; ViV: Valve-in-valve; TOF: Tetralogy of Fallot; DORV: Double outlet right ventricle; PS: Pulmonary stenosis; ASD: atrial septal defect.

Table 3. Hemodynamic data before and after PPVI

	Pre-procedure	Post-procedure	
Variables	Mean±SD	Mean±SD	*p*
Sistolic RVP	64.0±24.6	31.3±6.7	<0.001
RVOT gradient	44.0±23.2	7.6±5.8	<0.001
Sistolic RVP/Sistolic AoP	0.67±0.2	0.33±0.07	<0.001
PR degree*	2.1±1.2	0.2±0.4	<0.001

PPVI: Percutaneous pulmonary valve implantation; SD: Standard deviation; RVP: Right ventricle pressure; RVOT: Right ventricular outflow tract; AoP: Aortic pressure; PR: Pulmonary regurgitation; * Echocardiographic evaluation.

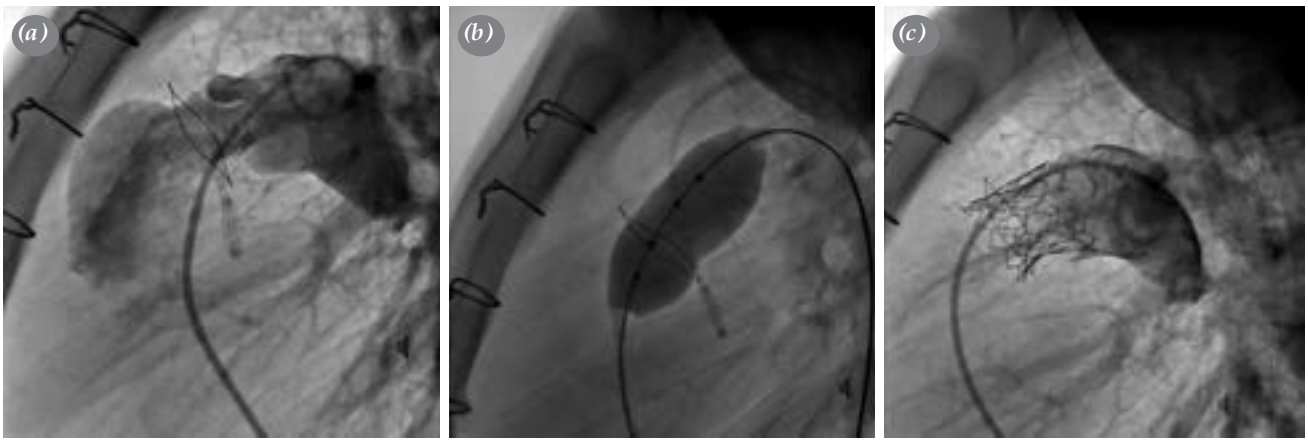

Figure 2. (a) Lateral view of injection from the distal part of the bioprosthetic valve. Stenosis and insufficiency are observed. **(b)** Image of the sizing balloon inflated along the length of the bioprosthetic valve. The stenotic area creates an indentation line. **(c)** Lateral view of injection after the implantation of the 26-mm Meril's Myval. No insufficiency is observed.

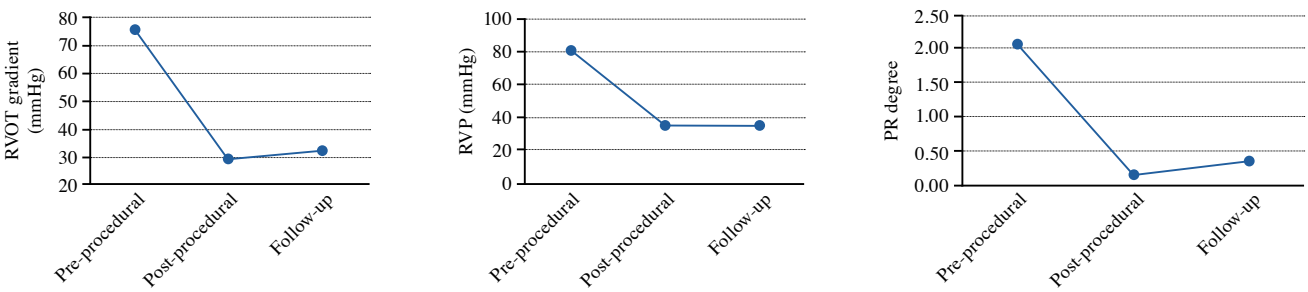

Figure 3. Echocardiographic evaluation of mean values before and after the procedure and during follow-up.
RVOT: Right ventricular outflow tract; RVP: Right ventricle pressure; PR: Pulmonary regurgitation.

The largest possible valve, based on the size of the initial BPV implanted, was selected for repeat procedures. The median size of the BPV used in the initial procedure was 23.0 mm (IQR, 21.8 to 25.0 mm), while the median size of the valves used in the percutaneous ViV procedure was 23.0 mm (IQR, 23.0 to 26.0 mm). A ViV larger than the previous BPV was implanted in six out of 20 patients. Of these patients, the previous pulmonary valve implantation was PPVI in four, and surgical in two patients. In one of the surgically implanted BPVs, the ring was fractured, and in the other patient, the fracture could not be determined. One of the four PPVI patients had Melody valves, and the other three had Edwards Sapien valves. As the same valve can be implanted

with different balloon-in-balloon catheters in the Melody valve system, it was possible to perform the implantation with a 22-mm balloon-in-balloon catheters in the patient who had previously received an 18-mm Melody valve. Overexpansion of the valve was observed in patients with the Edwards Sapien valve after balloon angioplasty. In all these, patients the stent configuration was distorted, but no significant fracture was observed. The median procedure time was 62.5 min (IQR, 36.3 to 75.0 min), and the median fluoroscopy time was 12.8 min (IQR, 9.0 to 21.5 min). The median length of hospital stay was 2 days (IQR, 1.25 to 2 days). The ViV procedure was successful in all patients without major complications. One patient had spontaneous resolution of a procedure-related pulmonary hemorrhage, and another had a brachial plexus injury that improved with physiotherapy and medical treatment. The latter patient's symptoms resolved during follow-up.

Echocardiographic and follow-up data

Within the first 24 h following the percutaneous ViV procedure, TTE demonstrated a significant decrease in RVPs compared to preprocedure levels, with a median of 29.0 mmHg (IQR, 35.0 to 41.3 mmHg) from a baseline of 80.0 mmHg (IQR, 60.0 to 90.0 mmHg; $p<0.001$). Similarly, there was a significant decrease in RVOT gradients, with a median of 30.0 mmHg (IQR, 28.8 to 40.0 mmHg) from a baseline of 75.0 mmHg (IQR, 65.0 to 92.5 mmHg; $p<0.001$). A notable improvement was observed in the degree of PR, and no patient had more than mild regurgitation.

The median follow-up was 24.8 months (IQR, 8.3 to 40.2 months). Overall, patients maintained good valvular function; none had a measured systolic RVP >45 mmHg or worse than mild regurgitation. The freedom from reintervention rate was 95%. Only one patient underwent repeat PPVI 10 years after ViV. No other patient required reintervention during follow-up. There were no cases of endocarditis. Time-dependent changes in echocardiographic variables are shown in Figure 3. At the last follow-up (median 24.8 months), the median RVP was 35 mmHg (IQR, 30.0 to 41.3 mmHg), and the median RVOT gradient was 32.5 mmHg (IQR, 25.0 to 40.0 mmHg). There was no change in the degree of PR compared to immediately after implantation. Postprocedural stent fractures were not observed on chest radiographs during the study period.

DISCUSSION

In pathologies involving RVOT obstructions, such as tetralogy of Fallot, chronic PR has been documented to have detrimental effects on the right ventricle in surgeries performed without preserving or utilizing a valve.[11] Therefore, surgery using a prosthetic valve or valved conduit in the RVOT is widely used to reduce or eliminate PR in these pathologies.[12,13] However, the lifespan of such implants is limited and failure inevitably occurs. As a result, young patients are exposed to multiple open heart surgeries and repeated interventions.[5,14,15] The morbidity associated with repeated sternotomy is not insignificant, and considering complex congenital heart disease patients, alternative methods must be considered.[16,17]

The number of patients with PVR is increasing in all adult hospitals in the USA, reflecting an overall increase in the adult population with congenital heart disease.[18] The number of PPVI procedures has recently increased, while the volume of surgical PVR has remained constant. However, comparative data between PPVI and surgical PVR are still limited, reflecting the heterogeneity of the patient populations. In most studies, complications, including in-hospital mortality, are higher in the surgical PVR group. In addition, the length of stay is significantly shorter in the PPVI group, which also contributes to lower wage loss with similar hospital costs.[18,19]

Although PPVI is a viable alternative to surgical PVR in other settings, the higher incidence of infective endocarditis after PPVI remains a significant concern. Meta-analyses have shown that surgical PVR is associated with a lower risk of postoperative infective endocarditis compared to PPVI.[20,21] The risk of infective endocarditis remains the most important issue to overcome with PPVI.[20]

Various percutaneous interventions have been initiated as alternatives to surgery. Bare metal stent implantation into dysfunctional valved conduits or BPVs has been used as a palliative treatment, particularly in lesions with predominant stenosis.[22,23] However, following this procedure, the RV continues to be exposed to the detrimental effects of PR, providing only short-term benefits.[24] In contemporary practice, PPVI is utilized as a catheter-based intervention to treat conduit dysfunction, whether it involves stenotic, regurgitant, or combined lesions.[25,26] Despite the successful outcomes of both surgical PVR and PPVI, dysfunction may develop in the implanted valves after a certain period.

In this study, we reported the results of successful ViV procedures in dysfunctional BPVs placed in the pulmonary position by transcatheter or surgical means.

Percutaneous ViV within a BPV accounts for approximately 6 to 7% of all PPVI patients, varying from center to center.[27,28] In a study reporting long-term PPVI outcomes from Australia and New Zealand, valves implanted into an existing BPV or biological conduit accounted for nearly 30% of all valves implanted.[26] In our study, the rate of percutaneous ViV within BPVs was 8.1%, and when evaluated in conjunction with conduits, it was approximately 28%, similar to studies in the literature. As reported in limited studies, there was a significant reduction in RVOT gradients and RV pressures, providing hemodynamic relief after the procedure[8,28] and an improvement in patients' clinical status and exercise capacity.

Theoretically, unlike homografts, BPVs have a fixed outer diameter that cannot be expanded. Cases have been reported in the literature where the BPV ring has been fractured using ultra-high-pressure balloons.[29,30] After the ViV procedure, the maximum inner diameter will be slightly less than the nominal diameter. Therefore, when placing a BPV, the size of the valve should be considered, particularly in the context of potential reinterventions, and the largest possible size should be selected. A study based on a multicenter experience evaluating the optimal BPV size suggested an ideal valve size of 27 mm,[31] but this is a preliminary finding based on a single study. Kwak et al.[32] demonstrated that patients under 20 years of age have a higher rate of valve dysfunction, even when larger BPVs are implanted, compared to the adult patient group, when considering implanted valve size and patient age. In another study, patients were grouped based on the implanted valve size, and despite smaller age and size, no significant difference in hemodynamic data was found at follow-up, similar to our study.[33] In our study, the widest valve was selected for placement within the BPV after determining the appropriate position. In patients who needed it, stenting before valve implantation and adding extra volume to the inflated balloon during valve placement allowed the widest valve size to be achieved. This approach aimed to clearly eliminate the stenosis in the BPV, achieving a wider outer ring size before repeated procedures. No fractures were observed in the BPV outer ring during the procedure or follow-up in any patient.

The literature suggests that postprocedural hemodynamic improvement is a time-dependent event[33,34] related to the resolution of postprocedural edema and hematoma after stent implantation. In our study, echocardiographic evaluation showed that the hemodynamic improvement was sustained both after the procedure and at the last follow-up compared to the preprocedure period. Furthermore, the fact that PR did not progress to a more advanced stage at follow-up was also an indicator of procedural success. This successful procedure appears to have sustained effects, at least in the short to medium term.

In valves placed within BPVs may require reintervention primarily due to stenosis, regurgitation, or a combined lesion. In a study evaluating the mechanisms of reintervention through a transcatheter approach in BPVs placed in the pulmonary position, involving 55 patients (41 surgical, 14 transcatheter), 54% of patients underwent the procedure due to combined lesions, 32% due to stenosis, and 14% due to at least moderate insufficiency. The reported freedom from reintervention rate over a median follow-up of 1.3 years for transcatheter valves was 94%,[35] and in another study, the rate over a median follow-up of 32 months was 81.5±12.0%.[8] A study reporting the results of Edwards Sapien XT transcatheter pulmonary valve implantation reported a reintervention rate of 12.8% over a five-year follow-up period.[36] In our center, a total of 124 patients underwent Edwards Sapien pulmonary valve implantation during the study period. Reintervention was required in eight (6.4%) patients during a median follow-up of 8.5 years. The mean time between initial procedure and reintervention was 6.9 years. Eight patients underwent reintervention for recurrent RVOT obstruction (four underwent ViV, two underwent balloon dilatation, and two underwent surgical valve replacement).

In our study, ViV procedures were performed in 60% of cases primarily for stenosis. The freedom from reintervention rate was 95% over a median follow-up duration of 24.8 months, which is quite promising compared to the literature. In another multicenter study, no patient required reintervention, over a median follow-up of approximately one year. Only one patient developed infective endocarditis with secondary PR, but no intervention was required.[33] In our study, a ViV procedure was performed only 10 years after transcatheter pulmonary valve implantation, primarily for stenosis. Infective endocarditis was not observed in any patient.

However, considering the risk of infective endocarditis posed by the bioprosthetic material placed in the RVOT, procedural-related complications are quite rare, mostly related to vascular access.[37] In our study, although no procedure-related complications were observed, one patient experienced a spontaneously resolving pulmonary hemorrhage during postprocedural follow-up, and another patient had a brachial plexus injury related to the position given during the procedure, which resolved with physiotherapy and medical treatment. The second patient's symptoms improved during follow-up.

This study had some limitations. The study was limited by its single-center retrospective design. The heterogeneity of the included patients, who had BPVs placed through both surgical and transcatheter methods, and the variability in the types of valves that underwent ViV procedures were major limitations. Initially, we performed PPVI only in patients with conduit and later in patients with native RVOT. As we gained experience, we started to perform ViV procedures as well. Therefore, the sample size was small, and the follow-up period for VIV was relatively shorter, although we started performing PPVI about 10 years ago.

In conclusion, this study demonstrated successful procedures with low complication and reintervention rates. Percutaneous ViV procedures within dysfunctional BPVs in the pulmonary position can be safely performed in experienced centers. Considering the potential risks associated with median sternotomy, this approach should be preferred in eligible patients. The success of the procedure does not appear to depend on the diameter of the implanted valve or the age of the patient. However, given the potential for reintervention, selecting the widest possible valve at the time of initial implantation appears to be a reasonable approach.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

1. Therrien J, Marx GR, Gatzoulis MA. Late problems in tetralogy of Fallot--recognition, management, and prevention. Cardiol Clin 2002;20:395-404. doi: 10.1016/s0733-8651(02)00010-3.
2. Piazza L, Chessa M, Giamberti A, Bussadori CM, Butera G, Negura DG, et al. Timing of pulmonary valve replacement after tetralogy of Fallot repair. Expert Rev Cardiovasc Ther 2012;10:917-23. doi: 10.1586/erc.12.67.
3. Vricella LA, Kanani M, Cook AC, Cameron DE, Tsang VT. Problems with the right ventricular outflow tract: A review of morphologic features and current therapeutic options. Cardiol Young 2004;14:533-49. doi: 10.1017/S1047951104005116.
4. Giugno L, Faccini A, Carminati M. Percutaneous pulmonary valve implantation. Korean Circ J 2020;50:302-16. doi: 10.4070/kcj.2019.0291.
5. Chen PC, Sager MS, Zurakowski D, Pigula FA, Baird CW, Mayer JE Jr, et al. Younger age and valve oversizing are predictors of structural valve deterioration after pulmonary valve replacement in patients with tetralogy of Fallot. J Thorac Cardiovasc Surg 2012;143:352-60. doi: 10.1016/j.jtcvs.2011.10.079.
6. Nomoto R, Sleeper LA, Borisuk MJ, Bergerson L, Pigula FA, Emani S, et al. Outcome and performance of bioprosthetic pulmonary valve replacement in patients with congenital heart disease. J Thorac Cardiovasc Surg 2016;152:1333-42.e3. doi: 10.1016/j.jtcvs.2016.06.064.
7. Lee C, Park CS, Lee CH, Kwak JG, Kim SJ, Shim WS, et al. Durability of bioprosthetic valves in the pulmonary position: Long-term follow-up of 181 implants in patients with congenital heart disease. J Thorac Cardiovasc Surg 2011;142:351-8. doi: 10.1016/j.jtcvs.2010.12.020.
8. Asoh K, Walsh M, Hickey E, Nagiub M, Chaturvedi R, Lee KJ, et al. Percutaneous pulmonary valve implantation within bioprosthetic valves. Eur Heart J 2010;31:1404-9. doi: 10.1093/eurheartj/ehq056.
9. Shahanavaz S, Berger F, Jones TK, Kreutzer J, Vincent JA, Eicken A, et al. Outcomes after transcatheter reintervention for dysfunction of a previously implanted transcatheter pulmonary valve. JACC Cardiovasc Interv 2020;13:1529-40. doi: 10.1016/j.jcin.2020.03.035.
10. Geva T. Repaired tetralogy of Fallot: The roles of cardiovascular magnetic resonance in evaluating pathophysiology and for pulmonary valve replacement decision support. J Cardiovasc Magn Reson 2011;13:9. doi: 10.1186/1532-429X-13-9.
11. Gregg D, Foster E. Pulmonary insufficiency is the nexus of late complications in tetralogy of Fallot. Curr Cardiol Rep 2007;9:315-22. doi: 10.1007/BF02938380.
12. O'Byrne ML, Glatz AC, Mercer-Rosa L, Gillespie MJ, Dori Y, Goldmuntz E, et al. Trends in pulmonary valve replacement in children and adults with tetralogy of fallot. Am J Cardiol 2015;115:118-24. doi: 10.1016/j.amjcard.2014.09.054.
13. Tweddell JS, Pelech AN, Frommelt PC, Mussatto KA, Wyman JD, Fedderly RT, et al. Factors affecting longevity of homograft valves used in right ventricular outflow tract reconstruction for congenital heart disease. Circulation 2000;102:III130-5. doi: 10.1161/01.cir.102.suppl_3.iii-130.

14. Batlivala SP, Emani S, Mayer JE, McElhinney DB. Pulmonary valve replacement function in adolescents: A comparison of bioprosthetic valves and homograft conduits. Ann Thorac Surg 2012;93:2007-16. doi: 10.1016/j.athoracsur.2012.02.039.
15. Caldarone CA, McCrindle BW, Van Arsdell GS, Coles JG, Webb G, Freedom RM, et al. Independent factors associated with longevity of prosthetic pulmonary valves and valved conduits. J Thorac Cardiovasc Surg 2000;120:1022-30. doi: 10.1067/mtc.2000.110684.
16. Holst KA, Dearani JA, Burkhart HM, Connolly HM, Warnes CA, Li Z, et al. Risk factors and early outcomes of multiple reoperations in adults with congenital heart disease. Ann Thorac Surg 2011;92:122-8. doi: 10.1016/j.athoracsur.2011.03.102.
17. Villa-Hincapie CA, Carreno-Jaimes M, Obando-Lopez CE, Camacho-Mackenzie J, Umaña-Mallarino JP, Sandoval-Reyes NF. Risk factors for mortality in reoperations for pediatric and congenital heart surgery in a developing country. World J Pediatr Congenit Heart Surg 2017;8:435-9. doi: 10.1177/2150135117704657.
18. Megaly M, Han K, Sedhom R, Aboulhosn J, Moga F, Mudy K, et al. Outcomes of percutaneous and surgical pulmonary valve implantation. Cardiovasc Revasc Med 2021;32:27-32. doi: 10.1016/j.carrev.2020.12.035.
19. Chatterjee A, Bhatia N, Torres MG, Cribbs MG, Mauchley DC, Law MA. Comparison of transcatheter pulmonic valve implantation with surgical pulmonic valve replacement in adults (from the National Inpatient Survey Dataset). Am J Cardiol 2020;125:135-9. doi: 10.1016/j.amjcard.2019.09.031.
20. Çekirdekçi EI, Bugan B, Onar LÇ, Çekirdekçi A. Infective endocarditis after transcatheter approach versus surgical pulmonary valve replacement: A meta-analysis. Turk Gogus Kalp Dama 2022;30:472-83. doi: 10.5606/tgkdc.dergisi.2022.23506.
21. McElhinney DB. Reflection and Rationalization: Making Sense of the Literature on Endocarditis After Transcatheter Pulmonary Valve Replacement. Circ Cardiovasc Interv 2017;10:e004983. doi: 10.1161/CIRCINTERVENTIONS.117.004983.
22. Carr M, Bergersen L, Marshall AC, Keane JF, Lock JE, Emani SM, et al. Bare metal stenting for obstructed small diameter homograft conduits in the right ventricular outflow tract. Catheter Cardiovasc Interv 2013;81:E44-52. doi: 10.1002/ccd.24369.
23. Peng LF, McElhinney DB, Nugent AW, Powell AJ, Marshall AC, Bacha EA, et al. Endovascular stenting of obstructed right ventricle-to-pulmonary artery conduits: A 15-year experience. Circulation 2006;113:2598-605. doi: 10.1161/CIRCULATIONAHA.105.607127.
24. Aggarwal S, Garekar S, Forbes TJ, Turner DR. Is stent placement effective for palliation of right ventricle to pulmonary artery conduit stenosis? J Am Coll Cardiol 2007;49:480-4. doi: 10.1016/j.jacc.2006.09.037.
25. Ran L, Wang W, Secchi F, Xiang Y, Shi W, Huang W. Percutaneous pulmonary valve implantation in patients with right ventricular outflow tract dysfunction: A systematic review and meta-analysis. Ther Adv Chronic Dis 2019;10:2040622319857635. doi: 10.1177/2040622319857635.
26. Lawley CM, Tanous D, O'Donnell C, Anderson B, Aroney N, Walters DL, et al. Ten years of percutaneous pulmonary valve implantation in Australia and New Zealand. Heart Lung Circ 2022;31:1649-57. doi: 10.1016/j.hlc.2022.07.008.
27. Lurz P, Coats L, Khambadkone S, Nordmeyer J, Boudjemline Y, Schievano S, et al. Percutaneous pulmonary valve implantation: Impact of evolving technology and learning curve on clinical outcome. Circulation 2008;117:1964-72. doi: 10.1161/CIRCULATIONAHA.107.735779.
28. Tarzia P, Conforti E, Giamberti A, Varrica A, Giugno L, Micheletti A, et al. Percutaneous management of failed bioprosthetic pulmonary valves in patients with congenital heart defects. J Cardiovasc Med (Hagerstown) 2017;18:430-5. doi: 10.2459/JCM.0000000000000486.
29. Langhammer F, Lehner A, Haas NA, Jakob A. Percutaneous pulmonary valve implantation in a dysfunctional Trifecta® bioprothesis after high-pressure balloon fracturing. Catheter Cardiovasc Interv 2020;95:1310-3. doi: 10.1002/ccd.28781.
30. Tanase D, Grohmann J, Schubert S, Uhlemann F, Eicken A, Ewert P. Cracking the ring of Edwards Perimount bioprosthesis with ultrahigh pressure balloons prior to transcatheter valve in valve implantation. Int J Cardiol 2014;176:1048-9. doi: 10.1016/j.ijcard.2014.07.175.
31. Gillespie MJ, Rome JJ, Levi DS, Williams RJ, Rhodes JF, Cheatham JP, et al. Melody valve implant within failed bioprosthetic valves in the pulmonary position: A multicenter experience. Circ Cardiovasc Interv 2012;5:862-70. doi: 10.1161/CIRCINTERVENTIONS.112.972216.
32. Kwak JG, Lee C, Lee M, Lee CH, Jang SI, Lee SY, et al. Does implantation of larger bioprosthetic pulmonary valves in young patients guarantee durability in adults? Durability analysis of stented bioprosthetic valves in the pulmonary position in patients with Tetralogy of Fallot†. Eur J Cardiothorac Surg 2016;49:1207-12. doi: 10.1093/ejcts/ezv298.
33. Cabalka AK, Asnes JD, Balzer DT, Cheatham JP, Gillespie MJ, Jones TK, et al. Transcatheter pulmonary valve replacement using the melody valve for treatment of dysfunctional surgical bioprostheses: A multicenter study. J Thorac Cardiovasc Surg 2018;155:1712-24.e1. doi: 10.1016/j.jtcvs.2017.10.143.
34. Rodés-Cabau J, Houde C, Perron J, Benson LN, Pibarot P. Delayed improvement in valve hemodynamic performance after percutaneous pulmonary valve implantation. Ann Thorac Surg 2008;85:1787-8. doi: 10.1016/j.athoracsur.2007.11.007.
35. Callahan R, Bergersen L, Baird CW, Porras D, Esch JJ, Lock JE, et al. Mechanism of valve failure and efficacy of reintervention through catheterization in patients with bioprosthetic valves in the pulmonary position. Ann Pediatr Cardiol 2017;10:11-7. doi: 10.4103/0974-2069.197049.
36. Le Ruz R, Plessis J, Houeijeh A, Baruteau AE, Le Gloan L, Warin Fresse K, et al. Edwards SAPIEN XT transcatheter pulmonary valve implantation: 5-Year follow-up in a French Registry. Catheter Cardiovasc Interv 2021;98:990-9. doi: 10.1002/ccd.29862.
37. McElhinney DB, Hellenbrand WE, Zahn EM, ones TK, Cheatham JP, Lock JE, et al. Short- and medium-term outcomes after transcatheter pulmonary valve placement in the expanded multicenter US melody valve trial. Circulation 2010;122:507-16. doi: 10.1161/CIRCULATIONAHA.109.921692.